SM-402 REVISION HISTORY

Date of Revision	Page(s)/Section(s) Revised	Revision Explanation
01AUG2011		
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31OCT2017	All	Cosmetic Only
26MAR2019	All	Minor corrections and updates.

SM-402 STANDARD OPERATING PROCEDURE FOR SUBJECT RECRUITMENT AND SCREENING

I. INTRODUCTION AND PURPOSE

The recruitment phase of a clinical study is frequently difficult and challenging. Successfully recruiting subjects involves the development and implementation of a well-coordinated plan that may require the efforts of the entire research team. Once in place, subject recruitment efforts must be constantly assessed, with new strategies implemented as necessary. After potential subjects have been identified through recruitment efforts, the process of subject selection begins.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in subject recruitment and selection.

2. SCOPE

This SOP applies to the activities involved in recruiting and screening subjects for clinical studies conducted at this investigative site subject to investigational new drug (IND) regulations for drugs and biologics during all phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.20	General requirements for informed consent
21 CFR 56.109	IRB review of research
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention

4. REFERENCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team
SS-201	Assessing Protocol Feasibility
SS-204	Protocol Start-Up
PM-303	Regulatory Files and Subject Records
SM-401	Informed Consent Development and Implementation
SM-403	Subject Management While on Study

5. ATTACHMENTS

A. Screening and Enrollment Log

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in conducting clinical trials at this research site. This includes the following:

- Principal investigator
- Sub-investigator
- Research coordinator
- Support staff

7. DEFINITIONS

The following definitions from the International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline apply to this SOP.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

Subject/Trial Subject: An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

Vulnerable Subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

8. PROCESS OVERVIEW

A. Develop and implement an overall recruitment plan
B. Assess the effectiveness of the recruitment plan
C. Initiate screening procedures

9. PROCEDURES

A. DEVELOP AND IMPLEMENT AN OVERALL RECRUITMENT PLAN

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research Director/Manager Research coordinator	Based upon the specific inclusion/exclusion criteria for a study, identify the target population for potential study subjects. Establish a recruitment timeline. Identify sources of potential participants.
Research coordinator Support staff	Determine recruitment methods (e.g., space/radio ads, letters, community talks, newspaper articles, patient support groups, social media, internet). Develop recruitment materials and submit to the IRB as appropriate.

Research Director/Manager Research coordinator	Project costs associated with each recruitment strategy. Hire additional staff if necessary and provide training.

B. ASSESS THE EFFECTIVENESS OF THE RECRUITMENT PLAN

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research Director/Manager Research coordinator PI	Monitor progress and assess results of the recruitment strategy. Develop appropriate alternative strategies, if necessary. Institute alternative strategies if enrollment projections lag. Evaluate final results.

C. INITIATE SCREENING PROCEDURES

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Develop a screening log and/or phone screen based upon the study inclusion/exclusion criteria to collect screening information on all potential subjects (Attachment A, Screening and Enrollment Log). Note if individuals went on to enroll in the study; if they were not enrolled, document the reason.
PI Research coordinator	Obtain informed consent. Maintain a log of when informed consent was obtained from each subject. Retain all signed informed consent forms from subjects who terminate their participation in the study during the screening process.

ATTACHMENT A

SCREENING AND ENROLLMENT LOG

Screening				Enrollment			
Screen Date	**ID #**	**ICF Signed**	**Consented by**	**Enroll Date**	**ID #**	**If not enrolled, explain**	**Staff Initials**